REMARKS

Claims 1-4, 6-47 and 49-75 are pending in the present application, and stand rejected. This application continues to include claims 1-4, 6-47 and 49-75.

Reconsideration of the rejection of claims 1-4, 6-47 and 49-75 is respectfully requested.

Claims 1-4, 6-26, 30-43, 47 and 49-75 were rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster, et al. (U.S. Publication No. 2001/0034528; hereinafter Foerster) in view of Makower, et al. (U.S. Patent No. 6,090,063; hereinafter, Makower).

It appears that the Examiner relies on the tube 54 of Foerster as corresponding to the recited cannula and the marking instrument 10 having marking element 12/center wire 18 as corresponding to the recited localization wire, with distal end 20 of the center wire as corresponding to the recited insertion tip. In paragraph 4 of the final office action, the Examiner recognizes that Foerster does not disclose the recited actuator, handle, grip or biasing element (spring), for which the Examiner relies on Makower.

Notwithstanding, Foerster discloses a marking instrument (10) which includes marking element 12 which includes an umbrella end comprising a pair of attachment members or wings (14, 16), and a center wire (18). All three wires (14, 16, 18) are joined at the distal end (20) of the center wire (18). At the proximal end of center wire (18) is a deployment actuator or pull ring (24). (Para. [0041]; Figs. 4-8). The marking instrument (10) further includes a tube (54). The center wire (18) runs axially through a lumen (56) of tube (54), with the pull ring (24) being attached to the proximal end of the center wire (18), proximally of the tube (54). The distal end (20) of the center wire extends distally of the tube (54) and is joined to attachment members (14, 16). In operation, tube (54) of the marking instrument is inserted into the patient's body until the

distal end (20) of the center wire (18) approaches the predetermined location adjacent to or in the abnormal tissue or lesion. (Para. [0046], [0047]; Figs. 4-8). Tissue is then vacuumed into the tissue receiving port (42). Once the distal end (20) of the center wire reaches the targeted vacuumed tissue, the pull ring (24) is pulled away from the tissue. This action deploys the marker attachment members (14, 16) as they are forced into a die formed in the tip (62) of the tube. Tension is further applied to pull ring (24) until the distal end of the marker is fully deployed. Even after attachment members (14, 16) have been fully deployed, the pull ring (24) is still further pulled distally from the target tissue until the center wire (18) is sheared at a point of weakness or detent (72) which is established in the wire (18) proximally of the tip (20). Once failure has occurred, the pull ring (24) and the proximal portion (18') of the center wire may be discarded as they are severed from the marker element (12) and the remaining distal portion (18') of the center wire. (Para. [0047], [0048]; Figs. 4-8).

Makower, et al. discloses a method of inserting materials which are flaccid rather than rigid, "flaccid" being defined as inherently incapable of being driven into tissue by the application of axial force. (Col. 6, ll 45-49). Makower, et al. further discloses a device having a mechanism for feeding the filament through a conduit in such a manner that sufficient force is applied to the filament that it is forced into the desired site. (Abstract). Filament injection device (1) includes inner cannula (14) which provides support for flaccid filament (5). Inner cannula (14) is retained axially within a coaxial outer cannula (15) so as to allow for axial movement of the inner cannula. (Col. 3, ll 8-13; Fig. 2). Filament injection device (1) further includes a cutout window (16) in the proximal section of inner cannula (14) which exposes a small section of filament (5) and allows actuation pad (17) to couple filament (5) and inner cannula (14) to an actuator

mechanism (502). When in a depressed condition, actuating pad (17) engages filament (5) with inner cannula (14). Advancement of the filament (5) is by means of the action of the actuator mechanism (502), of actuating pad (17) to the left, and the advancement, along with actuating pad (17) of both inner cannula (14) and filament (5) such that a length of filament (5) equal to the distance (19) of motion of the actuating pad (17) is urged into the body tissue. (Col. 8, ll 60-67 – Col. 9, ll 6; Figs. 3A-C, 5). Retraction of distal segment (408) of inner cannula (14) is achieved by means of the force supplied by containment spring (412) in compression. The feeding action described above allows a high force per unit cross-sectional area to be applied in advancing filament (5) into the body tissue while a lower force is supplied by containment spring (412) to retract the distal segment (408) of inner cannula (14). (Col. 9, ll 21-29; Figs. 4A, 4B).

Thus, in summary, Foerster requires for cannula tube 54 to be stationary relative to element (12), such that the exposed attachment members or wings (14, 16) are pulled against the end of cannula tube (54) as center wire (18) is pulled by pull ring 24. In contrast, Makower requires the inner cannula carrying the flaccid filament (5) be movable to linearly reciprocate relative to filament (5) such that during advancement of the filament (5) by the action of the actuator mechanism (502) of actuating pad (17) both inner cannula (14) and filament (5) are advanced equal to the distance (19) of motion that the actuating pad (17) is urged, and the retraction of distal segment (408) of inner cannula (14) is achieved by means of the force supplied by containment spring (412) in compression. Thus, the Examiner's asserted combination of Foerster and Makower would render each other inoperable, since Foerster requires for cannula tube (54) to be stationary while Makower requires inner cannula (14) to be movable.

Accordingly, one skilled in the art would not attempt to combine Foerster with Makower in attempting to achieve the invention as recite in Applicants' claims. In essence, to attempt the combination would be tantamount to impermissible hindsight reconstruction of Applicants' claims.

Moreover, claim 1 recites in part, "a localization wire located within the lumen and having a distal end near the insertion tip when the cannula is in the insertion position, wherein the localization wire comprises at least one anchor adapted to hold the localization wire in the tissue mass; and an actuator in operable communication with the cannula and operable between a charged condition and a discharged condition to retract the cannula **to expose** the distal end of the localization wire to the tissue mass." (Emphasis added).

In contrast, in Foerster the marker element 12, which includes an umbrella end comprising a pair of attachment members or wings (14, 16) attached to center wire (18), is exposed to the tissue prior to and during insertion of marker element (12) into tissue without retracting cannula tube (54), and in Makower (which does not disclose an anchor) it is the advancement of the inner cannula that discharges the flaccid filament (5) and the retraction of distal segment (408) of inner cannula (14) is to reset the inner cannula relative to the flaccid filament (5) for the next advancement.

Accordingly, even if Foerster and Makower were combined (although Applicants contend that one skilled in the art would not be motivated to do so), Applicants respectfully submit that Foerster and Makower, taken alone or in combination, do not disclose, teach, or suggest the subject matter of claim 1.

Accordingly, for at least the reasons set forth above, claim 1 is allowable in its present form.

Claims 2-4, 6-26 and 30-35 depend, directly or indirectly, from claim 1, and thus are believed allowable for at least the reasons set forth above with respect to claim 1. In addition, claims 2-4, 6-26 and 30-35 further and patentably define the invention over the cited references.

For example, claim 19 recites, "The apparatus of claim 18 wherein the biasing element is a spring in operable communication with the trigger such that movement of the trigger from the ready position to the release position releases the spring from a compressed state to an expanded state to move the cannula from the insertion position to the implant position." (Emphasis added). In contrast, Foerster does not disclose a biasing element, and Makower discloses that the feeding action allows a high force per unit cross-sectional area to be applied in advancing flaccid filament (5) into the body tissue while a lower force is supplied by containment spring (412) to retract the distal segment (408) of inner cannula (14). (Col. 9, ll 21-29; Figs. 4A, 4B).

Accordingly, for at least these additional reasons, claim 19 is believed allowable in its own right.

Claim 36 recites in part, "a localization wire located within the lumen and having a distal end near the insertion tip when the cannula is in the insertion position, wherein the localization wire comprises at least one anchor adapted to hold the localization wire in the tissue mass; and an actuator operable between a charged condition and a discharged condition to effect movement of the cannula relative to the localization wire to expose the localization wire to the surrounding tissue mass at the distal end of the cannula; wherein the handle, the cannula, the localization wire, and the actuator form a self-contained implanting apparatus for implanting the localization wire

into the tissue mass, whereby the cannula is inserted into the tissue mass and the actuator is placed in the discharged condition to effect movement of the cannula relative to localization wire to expose the distal end of the localization wire to the tissue mass."

Accordingly, claim 36 is believed allowable for substantially the same reasons set forth above with respect to claim 1.

Claims 37-43, 47 and 49-59 depend, directly or indirectly, from claim 36, and thus are believed allowable for at least the same reasons set forth above with respect to claim 1 as applied to claim 36. In addition, claims 37-43, 47 and 49-59 further and patentably define the invention over the cited references.

For example, claim 41 recites, "The apparatus of claim 40 wherein the biasing element is a spring operably coupled to the trigger such that movement of the trigger from the ready position to the release position releases the spring from a compressed state to an expanded state to move the cannula from the insertion position to the implant position."

In contrast, Foerster does not disclose a biasing element, and Makower discloses that the feeding action allows a high force per unit cross-sectional area to be applied in advancing flaccid filament (5) into the body tissue while a lower force is supplied by containment spring (412) to retract the distal segment (408) of inner cannula (14). (Col. 9, ll 21-29; Figs. 4A, 4B).

Accordingly, for at least these additional reasons, claim 41 is believed allowable in its own right.

Claim 60 recites in part, "a localization wire pre-loaded within the lumen and having a distal end near the insertion tip; and an actuator connected to the cannula and operable between a charged condition and a discharged condition to effect relative movement of the cannula and the

localization wire to expose the distal end of the localizing wire; inserting the insertion tip of the cannula and the localization wire into the tissue mass; and operating the actuator to retract the cannula to expose a portion of the distal end of the localization wire to the tissue mass." (Emphasis added).

Claim 60 is believed allowable for substantially the same reasons set forth above with respect to claim 1.

Claims 61-75 depend, directly or indirectly, from claim 60, and thus are believed allowable for at least the same reasons set forth above with respect to claim 1 as applied to claim 60.

Accordingly, for at least the reasons set forth above, it is respectfully submitted that pending claims 1-4, 6-26, 30-43, 47 and 49-75 are patentable over Foerster in view of Makower under 35 U.S.C. 103(a).

Claims 27-29 and 44-46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster in view of Makower as applied to claim 25, and further in view of Truckai, et al. (U.S. Patent No. 6,813,520; hereinafter Truckai).

Claims 27-29 and 44-46 are believed allowable at least in view of their respective dependence from base claims 1 and 36, since Truckai does not overcome the deficiencies of Foerster and Makower with respect to claims 1 and 36.

Accordingly, for at least the reasons set forth above, it is respectfully submitted that pending claims 27-29 and 44-46 are patentable over Foerster in view of Makower, and further in view of Truckai, under 35 U.S.C. 103(a).

For the foregoing reasons, Applicants submit that the cited references do not render obvious the subject matter of the pending claims. The pending claims are therefore in condition for allowance, and Applicants respectfully request withdrawal of all rejections and allowance of the claims.

In the event Applicants have overlooked the need for an extension of time, an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby conditionally petition therefor and authorize that any charges be made to Deposit Account No. 20-0095, TAYLOR & AUST, P.C.

Should any question concerning any of the foregoing arise, the Examiner is invited to telephone the undersigned at (317) 894-0801.

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